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Achieve Life Sciences Announces Initiation of Phase 2b ORCA-1 Trial Evaluating Cytisinicline (cytisine) for Smoking Cessation

SEATTLE and VANCOUVER, British Columbia, Oct. 30, 2018 /PRNewswire/ -- Achieve Life Sciences, Inc. (Nasdaq: ACHV), a clinical-stage pharmaceutical company committed to the global development and commercialization of cytisinicline for smoking cessation, today announced initiation of the Phase 2b ORCA-1 trial for smoking cessation.



ORCA-1 is the first in Achieve's ORCA (*Ongoing Research of Cytisinicline for Addiction*) Program, that aims to evaluate the effectiveness of cytisinicline for smoking cessation and potentially other indications. This Phase 2b trial will evaluate both the 1.5mg and 3mg doses of cytisinicline on a declining titration schedule over 25 days, as well as three times daily dosing. The trial is randomized and blinded to compare the effectiveness of the cytisinicline doses and schedules to respective placebo groups. The primary efficacy endpoint is reduction in the number of cigarettes smoked during treatment with secondary analyses conducted on smoking cessation rates, safety, and compliance. ORCA-1 will evaluate approximately 250 smokers and is being conducted at eight centers across the U.S. Data results are expected in mid-2019.

"The initiation of the ORCA-1 trial demonstrates our continued progress and commitment to expeditiously developing cytisinicline as a treatment for smoking cessation in the U.S.," said Rick Stewart, Chairman and Chief Executive Officer of Achieve Life Sciences. "We intend to utilize our learnings from this trial to finalize the Phase 3 program, expected to begin later next year."

Additionally, Achieve announced the United States Adopted Names (USAN) Council adopted "cytisinicline" as the nonproprietary, or generic, name for cytisine. The USAN Council is responsible for selecting simple, informative, and unique generic drug names. They establish logical nomenclature classifications based on pharmacological and/or chemical relationships.

About Cytisinicline

Tobacco use is currently the leading cause of preventable death and is responsible for nearly six million deaths annually worldwide¹. It is estimated that 28.6% of all cancer deaths in the U.S. are attributable to cigarette smoking². Achieve's focus is to address the global smoking health epidemic through the development and commercialization of cytisinicline, also known as cytisine.

Cytisinicline is a plant-based alkaloid with a high binding affinity to the nicotinic acetylcholine receptor. It is believed to aid in smoking cessation by interacting with nicotine receptors in the brain by reducing the severity of nicotine withdrawal symptoms and by reducing the reward and satisfaction associated with smoking.

As an approved, branded product in Central and Eastern Europe for more than two decades, it is estimated that over 20 million people have used cytisinicline to help combat nicotine addiction.

ABOUT The ORCA Program

Achieve's ORCA (*Ongoing Research of Cytisinicline for Addiction*) Program is a series of clinical trials to advance the development and commercial availability of cytisinicline for smoking cessation and potentially other indications.

ORCA-1 is a Phase 2b Optimization Trial that is being conducted at eight trial locations throughout the United States to assess various dosing schedules of cytisinicline in approximately 250 smokers. It will evaluate efficacy based on the overall reduction in the number of cigarettes smoked during the various study treatment doses and schedules. It will also compare smoking cessation rates, compliance, and safety profiles, compared to the respective placebo groups. ORCA-1 initiated in October of 2018 and data results are expected in mid-2019. Results from this study will be used for defining future cytisinicline development.

Additional information on cytisinicline and the ORCA program can be found at www.achievelifesciences.com and www.orcaprogram.com.

Forward Looking Statements

This press release contains forward-looking statements within the meaning of the "safe harbor" provisions of the Private Securities Litigation Reform Act of 1995, including, but not limited to, statements regarding the planned cytisinicline clinical development activities, the timing of clinical development activities related to cytisinicline, the potential market size for cytisinicline and the potential benefits of cytisinicline. All statements other than statements of historical fact are statements that could be deemed forward-looking statements. Achieve may not actually achieve its plans or product development goals in a timely manner, if at all, or otherwise carry out its intentions or meet its expectations or projections disclosed in these forward-looking statements. These statements are based on management's current expectations and beliefs and are subject to a number of risks, uncertainties and assumptions that could cause actual results to differ materially from those described in the forward-looking statements, including, among others, the risk that cytisinicline may not demonstrate the hypothesized or expected benefits; the risk that Achieve may not be able to obtain additional financing to fund the development of cytisinicline; the risk that cytisinicline will not receive regulatory approval or be successfully commercialized; the risk that new developments in the smoking cessation landscape require changes in business strategy or clinical development plans; the risk that Achieve's intellectual property may not be adequately protected; general business and economic conditions; and the other factors described in the risk factors set forth in Achieve's filings with the Securities and Exchange Commission from time to time, including Achieve's Annual Reports on Form 10-K and Quarterly Reports on Form 10-Q. Achieve undertakes no obligation to update the forward-looking statements contained herein or to reflect events or circumstances occurring after the date hereof, other than as may be required by applicable law.

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"ORCA is a trademark of Achieve Life Sciences, Inc."

¹ World Health Organization. WHO Report on the Global Tobacco Epidemic, 2011, Geneva: World Health Organization, 2011.

² Annals of Epidemiology , Volume 25 , Issue 3 , 179 - 182.e1

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